

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

This Document Relates to All Actions

**DEFENDANTS ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.,
HUAHAI U.S., INC., PRINSTON PHARMACEUTICAL INC., AND SOLCO
HEALTHCARE U.S., LLC'S MEMORANDUM OF LAW IN SUPPORT OF
MOTION TO AMEND OR CORRECT THE COURT'S OPINION
ON THE PARTIES' LIABILITY EXPERTS**

INTRODUCTION

The Court’s recent decision excluding in part several of the liability experts in this case seems to contradict the age-old adage: “what is good for the goose is good for the gander.” According to the Court, Dr. Ali Afnan may not opine that the at-issue VCDs were not adulterated and were equivalent to Diovan because such testimony would constitute “legal opinions.” At the same time, however, plaintiffs’ experts *can* opine that the at-issue VCDs were adulterated and not equivalent to Diovan. Because that disparate treatment violates fundamental notions of fairness, and because Dr. Afnan’s opinions do not constitute legal opinions in the first place, defendants respectfully request that this Court amend or correct its ruling to allow both sides’ experts to testify on the topics of adulteration and equivalence. Alternatively, if one side’s experts cannot testify on these topics, the same restriction should apply to both.

First, the Court applied different standards to plaintiffs’ and defendants’ experts in its recent *Daubert* ruling, excluding several of Dr. Afnan’s opinions as “legal opinions,” while allowing Drs. Ramin Najafi and Laura Plunkett to offer the opposite opinions. All three of these experts opine one way or the other on adulteration: Drs. Najafi and Plunkett declare the at-issue VCDs are “adulterated,” while Dr. Afnan disagrees that plaintiffs’ experts have support for their position and considers the products not adulterated. But the Court has decided that only

plaintiffs' experts can decree whether a product is adulterated, while Dr. Afnan apparently cannot testify to the contrary. The Court also affords this same disparate treatment to Dr. Afnan's and Dr. Najafi's opinions on equivalence, barring Dr. Afnan from discussing the concept but giving Dr. Najafi free rein. Barring (or admitting) only one side's experts for reasons applicable to both sides violates fundamental notions of fairness and unfairly forces the parties onto unequal footing.

Second, even putting aside the disparate treatment of plaintiffs' and defendants' experts, Dr. Afnan's excluded opinions do not constitute legal opinions in the first place. Scores of courts in the Third Circuit and around the country have repeatedly allowed FDA regulatory experts to testify regarding regulatory requirements to assist the jury in understanding the FDA's complex and relatively unapproachable framework. Dr. Afnan is not trying to tell the jury what opinions they should reach on liability, but instead seeks to help them understand the regulatory scheme underlying the facts of this case.

BACKGROUND

On January 5, 2024, this Court issued an opinion excluding in part several of the parties' liability experts' opinions. (*See generally ECF No. 2581.*) As the Court explained, while the experts may "testify about a 'fact' that arises from their chemical, medical, toxicological, regulatory, etc. expertise," they may not testify

“as to the LEGAL MEANING, i.e., the liability meaning, of the lack of such guidance.” (*Id.* at 6.)

The Court excluded several of defense expert Dr. Afnan’s opinions “because they cross[ed] over into legal opinions . . . which he is unqualified to assert.” (*Id.*) In particular, the Court will not allow Dr. Afnan to testify “that the VCDs were not adulterated.” (*Id.*; *see also, e.g.*, Am. Rep. of Ali Afnan, Ph.D. (“Afnan Rep.”) ¶¶ 24, 138, Jan. 11, 2023 ([ECF No. 2286-3](#) at Ex. 13).)¹ Although Dr. Afnan relies on the statutory definition of adulteration in coming to his opinion that the VCDs were not adulterated (*see* Afnan Rep. ¶ 206), the Court considered Dr. Afnan’s opinion that the VCDs were not adulterated to not be “based on an FDA’s or other legal body’s determination” ([ECF No. 2581](#) at 6). Further, the Court will not allow Dr. Afnan to make “any assertion of therapeutical equivalence about VCDs and the RLD, Diovan” ([ECF No. 2581](#) at 6) and has excluded his opinion that “the

¹ The Court similarly ruled that Teva’s expert, Dr. Roger Williams, cannot opine that Teva’s VCDs “were not adulterated or misbranded” (Rep. of Roger Lea Williams, M.D. ¶ 136, Jan. 28, 2023 ([ECF No. 2295-3](#) at Ex. 1)) since it constitutes a “legal opinion” ([ECF No. 2581](#) at 17), and barred Teva’s expert, Timothy Anderson, from testifying about “the meaning and interpretation of FDA regulations and on the FDA definition of adulteration and on how the FDA applies that definition to drugs that contain contaminants not included in the Orange Book formulation” (*id.* at 8.).

presence of trace impurities in a generic drug or drug component does not affect bioequivalence” (Afnan Rep. ¶ 24).²

As to plaintiffs’ expert Dr. Najafi, by contrast, the Court takes no issue with his telling the jury that “[t]he Valsartan containing products were adulterated” since they “were not manufactured in accordance with current good manufacturing practices.” (Rep. of Ramin Najafi, Ph.D. (“Najafi Rep.”) at 38, Oct. 31, 2022 ([ECF No. 2292-6](#)).) Similarly, the Court will allow plaintiffs’ other expert, Dr. Plunkett, to tell the jury “that valsartan API and finished drug products manufactured and marketed by Defendants were ‘adulterated’ due to the presence of nitrosamine impurities” (Rep. of Laura M. Plunkett, Ph.D., DABT (“Plunkett Rep.”) ¶ 62, Oct. 31, 2022 ([ECF No. 2285-3](#))) and explicitly stated that Dr. Plunkett may “opine on the meaning of adulteration” to the jury ([ECF No. 2581](#) at 23). Both experts relied on the same statutory definition as Dr. Afnan in coming to their opinions about whether the at-issue VCDs were adulterated. (*See, e.g.*, Najafi Rep. at 11-12; Plunkett Rep. ¶ 25.)

Likewise, although the Court will not allow Dr. Afnan to make any assertion regarding the therapeutical equivalence between generic Valsartan and Diovan or

² The Court similarly barred defendants’ shared expert, Dr. Michael Bottorff, from “[u]sing, defining, explaining the term ‘therapeutic equivalence’ or clarifying his interpretation of that term.” ([ECF No. 2581](#) at 11.)

offer his opinion that trace impurities do not affect bioequivalence, it does not take issue with Dr. Najafi doing so. Indeed, among Dr. Najafi's admitted opinions are his assertions that “[g]eneric valsartan with NDMA and/or NDEA is not chemically or pharmaceutically equivalent to the approved formulation and impurity profile of brand name RLD/Diovan” and that “[t]he Valsartan containing products that contained NDMA and NDEA were not the same as the approved formulation and impurity profiles of Diovan.” (Najafi Rep. at 39.) The Court does not mention these opinions in its discussion of Dr. Najafi's opinions. (See [ECF No. 2581](#) at 21-22.)

ARGUMENT

“A district court may alter a prior decision due to the need to correct a clear error of law or fact or to prevent manifest injustice.” *Sheehan v. Del. & Hudson Ry. Co.*, 439 F. App’x 130, 133 (3d Cir. 2011). Similarly, “[a] trial judge has the discretion to reconsider an issue and should exercise that discretion whenever it appears that a previous ruling, even if unambiguous, might lead to an unjust result.” *Id.* (citation omitted). Further, “[i]t is an abuse of discretion ‘to exclude the otherwise admissible opinion of a party’s expert on a critical issue, while allowing the opinion of his adversary’s expert on the same issue.’” *United States v. Lankford*, 955 F.2d 1545, 1552 (11th Cir. 1992) (citation omitted). Indeed,

“fairness demands that if experts are presented, the jury must receive a full presentation on both sides of an issue.” *Id.* at 1553.

I. THE COURT DID NOT PROVIDE EQUAL TREATMENT TO PLAINTIFFS’ AND DEFENDANTS’ EXPERTS.

The Court’s inconsistent rulings on similar opinions affords plaintiffs favorable treatment. In particular, while the Court excluded several of Dr. Afnan’s opinions regarding adulteration and the equivalence between the at-issue VCDs and Diovan “because they cross over into legal opinions . . . which he is unqualified to assert,” the Court takes no issue with Drs. Najafi and Plunkett opining that the VCDs were adulterated and not equivalent to Diovan. ([ECF No. 2581](#) at 6.) Allowing plaintiffs’ experts to opine whether the VCDs meet the definition of adulteration or were equivalent to Diovan without allowing defendants to meet those opinions with their own expert evidence, introduces unfairness into the trial and presents grounds for reversal in the event of a verdict for plaintiffs. *See Lankford*, 955 F.2d at 1551-52 (remanding for new trial and reversing exclusion of defense expert “[b]ecause the government was allowed to offer expert testimony on the reasonable tax implications of a ‘campaign contribution,’ but the defense was not”).

As explained above, Dr. Afnan and Drs. Najafi and Plunkett essentially represent two sides of the same coin—while Dr. Afnan opines that the VCDs did not meet the statutory definition of adulteration, Drs. Najafi and Plunkett opine that

they did. Indeed, among Dr. Najafi's admitted opinions is his statement that the VCDs "were adulterated" because they "were not manufactured in accordance with current good manufacturing practices." (Najafi Rep. at 38.) Dr. Plunkett similarly plans to tell the jury that the VCDs "were 'adulterated' due to the presence of nitrosamine impurities." (Plunkett Rep. ¶ 62.) On the other hand, Dr. Afnan disagrees, opining that plaintiffs' experts "lack support for the assertion that generic valsartan API was adulterated at the time of sale" since "[w]hether a pharmaceutical drug is adulterated is a determination made by the FDA," and "a drug cannot be retroactively deemed adulterated for purposes of litigation." (Afnan Rep. ¶ 138.)

Despite these experts offering what amounts to the same type of opinion—whether the VCDs were adulterated—and basing those opinions on the same definition of "adulterated," the Court found that only defendants' expert is offering a "legal opinion[]." ([ECF No. 2581](#) at 6.) According to the Court, when Drs. Najafi and Plunkett declare to the jury that the VCDs meet the statutory definition of "adulterated" they are offering proper expert opinion that "arises from [their] expertise" (*id.* at 23; *see also id.* at 21), but when Dr. Afnan meets that opinion by explaining that plaintiffs' experts lack support for opinions on adulteration, he has crossed the line "into legal opinions." (*Id.* at 6.)

Those rulings are inconsistent and irreconcilable. If Dr. Afnan cannot opine that the VCDs were *not* adulterated because it “cross[es] over into legal opinions . . . which he is unqualified to assert” and because his opinions are “not based on FDA’s or other legal body’s determination,” then plaintiffs’ experts should not be allowed to opine that the VCDs *were* adulterated when they relied on the same statutory definition of “adulteration.” ([ECF No. 2581](#) at 6.) The same is true regarding equivalence. Again, the Court held that Dr. Afnan entered the realm of “legal opinion[]” by making assertions about bioequivalence and therapeutical equivalence (*id.*); by contrast, it found that Dr. Najafi asserting the opposite was proper expert testimony. (*See* Najafi Rep. at 39.)

Accordingly, defendants respectfully request that the Court allow Dr. Afnan to offer opinions on whether the VCDs were adulterated and equivalent to Diovan, just as it is allowing plaintiffs’ experts to do. Alternatively, if one side is precluded from offering such opinions, the same result should hold for both sides.

II. DR. AFNAN’S OPINIONS DO NOT CONSTITUTE INADMISSIBLE LEGAL CONCLUSIONS.

Even putting aside the disparities in the Court’s ruling, Dr. Afnan’s testimony regarding bioequivalence and adulteration should be admitted because he does not seek to offer inadmissible legal conclusions. Courts in this Circuit and around the country “have repeatedly allowed FDA regulatory experts to testify regarding regulatory requirements.” *In re Suboxone (Buprenorphine*

Hydrochloride & Naloxone) Antitrust Litig., No. 13-MD-2445, 2020 WL 6887885, at *45 (E.D. Pa. Nov. 24, 2020); *see, e.g., Bartoli v. Novartis Pharms. Corp.*, No. 3:13-0724, 2014 WL 1515870, at *7 (M.D. Pa. Apr. 17, 2014) (FDA expert “may testify as to the FDA regulatory scheme”); *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 461 F. Supp. 2d 271, 278-79 (D.N.J. 2006) (admitting “general information regarding the FDA’s regulation of prescription drug labeling” and the extent to which pharmaceutical company complied with it); *Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 658, 660 (E.D. Pa. 2012) (admitting testimony on “FDA regulation and [the defendant’s] regulatory compliance”); *Robinson v. Ethicon, Inc.*, 588 F. Supp. 3d 726, 736 (S.D. Tex 2022) (allowing the expert “to testify about what the regulations require and [the defendant’s] conduct with regard to the regulations” and to “use the terms ‘adulterated’ and ‘misbranded’ to demonstrate to the jury what the regulations require”). If such testimony is to be limited at all, it should only be limited to the extent it offers “final legal conclusions.” *Robinson*, 588 F. Supp. 3d at 736; *see In re Suboxone*, 2020 WL 6887885, at *46.

The opinions the Court excluded from Dr. Afnan easily fall on the admissible side of any line because they use terms of art like “adulterated” and “therapeutically equivalent” to discuss “what the regulations require” and how those regulations apply to ZHP’s conduct, without offering direct legal conclusions. The Court’s sua sponte order expressly excluded not just specific

legal conclusions, but also anything that would “imply, hint, or suggest” a legal meaning, a holding that goes much further than the relevant precedents. ([ECF No. 2581](#) at 6.) In addition, the specific sections of Dr. Afnan’s report that the Court targeted do not directly answer questions reserved for the Court in interpreting the law, or the jury in determining the facts. For example, the Court excluded the opinion that “[w]hether a pharmaceutical drug or API is adulterated is a determination made by the FDA.” (Afnan Rep. ¶ 24; *see id.* ¶ 138 (similar).) It also excluded opinions that “impurities” do not “affect bioequivalence” (*id.*) and that the at-issue VCDs “continue to be considered therapeutically equivalent” to Diovan (*id.* ¶ 69). And it struck Dr. Afnan’s opinion that a guidance document “does not provide legally enforceable requirements.” (*Id.* ¶ 53.) All of this testimony is “helpful to the jury” “in light of the complex nature of the FDA framework,” *In re Suboxone*, 2020 WL 6887885, at *45 (citations omitted), and none of it crosses the line into telling the jury the result it should reach or telling the Court exactly how regulations should be interpreted.

For this reason, too, the Court should revise its order and deny plaintiffs’ motion to exclude Dr. Afnan in full.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the Court amend or correct its ruling on the parties' liability experts to allow defendants' experts to offer opinions of the same kind and character as plaintiffs' experts.

Dated: January 17, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 17, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Jessica Davidson

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